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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
FIERRO, ALICIA	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/591,658	YUASA ET AL.	
	Examiner	Art Unit	
	Alicia L. Fierro	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10 and 12-19* is/are pending in the application.

4a) Of the above claim(s) *12 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 7-10* is/are rejected.

7)☒ Claim(s) *5,6 and 13-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/1/06, 5/17/07 and 11/26/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The instant application is a 35 USC §371 filing of international application No. PCT/JP04/002750, which was filed on March 4, 2004.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on May 17, 2007 and November 26, 2007 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, these IDS documents were considered and signed copies of form 1449 have been enclosed herewith. The information disclosure statement submitted on December 1, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed be submitted to the office. It has been placed in the application file, but the references which are crossed out in the signed copy of the 1449 form have not been considered because they have not been provided in English (documents AO and AP) or a copy has not been provided (document AS).

Restrictions/Elections

Applicant's election with traverse of Group I, Claims 1, 3-10 and 13-16 in the reply filed on April 10, 2009 is acknowledge. The election of the following species in the same reply is also acknowledged:

The cationized metalloporphyrin complex is [5,10,15,20-tetrakis(2-methylpyridyl)porphyrin] wherein R1-R4 are 2-methyl pyridyl); M is Fe; the anionic surfactant is steric acid; and the cholesterol is cholesterol.

The traversal is on the ground(s) that the office did not consider the contribution of each invention, as a whole, in alleging the lack of a special technical feature and that the office has not provided any indication that the contents of the claims, in making the allegation of lacking unity, were interpreted in light of the specification. This is found to be persuasive, in part, specifically with regards to the first traversal.

With regards to the first traversal, it is noted that the combination of prior art used to show lack of unity in the instant claims does not encompass all limitations (and thus the special technical feature) of the first claim. Specifically, claim 1 recites the technical feature which is common to claims across all groups I-III. Although Applicant's arguments were found to be persuasive, it has been determined that the claims still do not have unity of invention in light of new prior art found. Specifically, Nishihara et al. (US 2002/0164379), teach a cationized metalloporphyrin complex embedded in a liposome with the addition of an anionic surfactant and Baroli et al. (*International Journal of Pharmaceutics* 183 (1999)) teach that niosomes are preferable to liposomes because, while they have similar utilities and can be prepared in a similar fashion, niosomes have been shown to have increased chemical stability in comparison to liposomes. As such, it would have been *prima facie* obvious to one of ordinary skill in the art to make the instant invention by embedded the cationized metalloporphyrin complex taught by Nishihara in a niosome to increase chemical stability. Please see paragraphs 10-13 below for a

full analysis of the lack of contribution of the instant invention over the prior art of record. As a result, claim 1 lacks a general inventive step and Groups I-III lack a special technical feature.

With regards to the second traversal, the Examiner is not required to explicitly state that the claims were interpreted in light of the description, as that is the standard for interpreting the claims to determine lack of unity. However, the Examiner asserts that the claims were interpreted in light of the description but limitations from the specification have not been read into the claims for determination of lack of unity.

With regards to the election of species, Applicant's traversal is on the grounds that the Office has not provided any reasons or examples to support a conclusion that the species are patentably distinct. Upon further consideration, the requirement for election of a particular species is **withdrawn**.

In conclusion, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention.

The restriction requirement is still deemed proper and is therefore made **FINAL**.

Status of the Claims

3. Currently, Claims 1, 3-10 and 12-19 are pending in the instant application. Claims 12 and 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/10/09.

4. Claims 1, 3-10 and 13-16 read on an elected invention and species and are therefore under consideration in the instant application.

Claim Objections

5. Claims 5, 6 and 13-16 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not serve as the basis for any other multiple dependent claim, either directly or indirectly. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections – 35 USC §112

(Second Paragraph)

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3, 4 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 1, it is unclear what is meant by the term "niosome-forming substance." No definition is given in the specification other than saying that "many compounds reported to produce a niosome can be used" (p. 6, lines 7-8). There is no

indication of where such reports could be found, what properties are required to be present in order for a substance to be considered a niosome-forming substance. Since it is commonly known in the art that nonionic surfactants, with or without cholesterol, can be used to produce niosomes, the term will be interpreted as such for the purposes of applying art.

b. Regarding claim 1 (and dependent claims 3, 4 and 7-10), the wording of the claim is such that it is unclear whether the claim requires that the cationized metalloporphyrin complex forms an ion complex only with the anionic surfactant or if said complex would also include the noisome-forming substance. If Applicant intends to claim a niosome wherein the niosome-forming substance is *not* included in the ion complex, it is suggested that the claim be amended to read: "A metalloporphyrin complex-embedding niosome comprising a niosome-forming substance and a cationized metalloporphyrin complex which forms an ion complex with an anionic surfactant."

c. Regarding claim 1 (and dependent claim 10), it is unclear if the anionic surfactant is required to be present in the niosome. The phrase "which forms an ion complex with an anionic surfactant" appears to be a functional limitation on the cationized metalloporphyrin complex. Since the claims are not process claims, the step of "forming an ion complex" is considered to be an intended use or functional capability of the metalloporphyrin complex rather than requiring the presence of the anionic surfactant. Thus, for the purposes of applying art, the Examiner will interpret claim 1 as being drawn to a metalloporphyrin complex-embedding niosome comprising a cationized metalloporphyrin complex which can form an ion complex with an anionic surfactant and

claim 10 as specifically limiting which anionic surfactants the metalloporphyrin complex can bind to. If Applicant intends to claim a niosome which requires the presence of the anionic surfactant, the Examiner suggests amending the claim to read: "A metalloporphyrin complex-embedding niosome comprising a niosome-forming substance, a cationized metalloporphyrin complex, and an anionic surfactant." If Applicant intends to require the presence of the ion complex, the Examiner suggests amending the claim to read: "A metalloporphyrin complex-embedding niosome comprising a niosome-forming substance and an ion complex consisting of a cationized metalloporphyrin complex and an anionic surfactant."

d. Regarding claims 7 and 8, in defining the nonionic surfactant to be used, the phrase "one or more of" is used. This phrase renders the claim indefinite because claim 3, from which the rejected claims depend, recites the limitation that "the noisome-forming substance is *a* nonionic surfactant or a mixture of *a* nonionic surfactant and a cholesterol or a triacylglycerol" (emphasis added). Thus, it is unclear how the nonionic surfactant, as defined in claims 7 and 8 could be more than one of the particular surfactants listed. The Examiner suggests that the phrase "is one or more of" be amended to a proper Markush phrasing which reads "is selected from the group consisting of."

Claim Rejections - 35 USC § 112

(First Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the elements "cationized metalloporphyrin complex" and "niosome-forming substance." Applicant has not described either claimed genus in a manner that would indicate they were in possession of the full scope of either genus, or even to describe what the genuses are comprised of.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter aria*, "functional characteristics when coupled with a known or disclosed correlation between function and

structure..." Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claims are drawn to a metalloporphyrin-embedding niosome comprising a cationized metalloporphyrin complex and a niosome-forming substance. The claimed "cationized metalloporphyrin complex" and "niosome-forming substance" encompass any metalloporphyrin complex and niosome-forming substance, both known and unknown. With regards to the niosome-forming substance, Applicants describe only that "many compounds reported to produce a niosome can be used" (p. 6, lines 7-8 of specification), and further give the example of nonionic surfactants or a mixture of nonionic surfactant and cholesterol or triacylglycerol. However, the examples described are only put forth as preferences and thus do not limit the definition of the claimed "niosome-forming substance." Based on Applicant's lack of description of this term other than non-limiting examples, it is not evident what other substances would be encompassed by this term/claim other than a nonionic surfactant. Applicants describe no "niosome-forming substances" other those specifically disclosed as examples. Further there is no disclosure of a method for using *any* niosome-forming substance other than nonionic surfactants. Thus, no niosome-forming substances, other than those described by providing examples on page 6, are described adequately enough to allow one skilled in the art to ascertain that Applicant is in possession of the entire scope of the claimed genus. Similarly, with regards to the cationized metalloporphyrin complex, this broad term

encompasses metalloporphyrin complexes which are not yet known in the art. Additionally, no metalloporphyrin complex is described adequately enough to determine possession of the entire scope, other than those of Formulae (I), (II), and (III). As such, Applicants have not described either genus in a manner that would allow one skilled in the art to immediately envisage all the compounds and niosome-forming substances contemplated for use. As such, the claims lack adequate written description for the myriad of compounds and niosomes embraced by the claimed "cationized metalloporphyrin complex" and "niosome-forming substance."

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections – 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3 and 7-9 are rejected under 35 U.S.C. 103(a) as obvious over Nishihara et al. (US 2002/0164379), publication date November 7, 2002, in view of Baroli et al. *International Journal of Pharmaceutics*. 183 (1999).

11. Nishihara et al. teaches cationic metalloporphyrin complexes (see, for example, the complex of formula (4) on page 6) embedded in liposomes. The liposomes used can be lipid endoplasmic reticulum, and particular examples are given such as phosphatidyl choline, phosphatidyl serine, and others ([0071]). Nishihara et al. also teaches that additional components

can be added to the liposome, such as dicetyl phosphate (a known anionic surfactant) and cholesterol ([0072]).

12. The difference between Nishihara et al. and the instant claims is that Nishihara does not teach a niosome or a niosome-forming substance.

13. Baroli et al. discusses generally the utility of niosomes. They disclose that although liposomes tend to be the most used vesicular carrier systems, non-ionic surfactant vesicles (or niosomes) are being extensively studied due to their useful properties. Niosomes "are widely studied as an alternative to liposomes because they can be prepared in the same way as phospholipid vesicles [liposomes], but they generally show higher chemical stability" (p.101, right-102, left, line 1). This reference teaches hexasubstituted cyclophosphazene compounds as niosome-forming substances (see abstract, lines 1-3). Although these compounds are not explicitly disclosed as being non-ionic surfactants, a person of ordinary skill in the art would readily recognize the compounds synthesized in the Baroli reference to be nonionic surfactants. In order to successfully form niosomes, the cyclophosphazene derivatives were combined with cholesterol in the presence of dicetylphosphate (an anionic surfactant) to prevent aggregation and subsequently stirred and sonicated (p. 103, section 3.2). Finally, Baroli et al. teach that, using the cyclophosphazene derivatives as niosome-forming substances, vesicles (i.e. niosomes) which have the ability to entrap both hydrophilic and lipophilic compounds (even those with low encapsulation efficiencies) were formed (p.106, see section 4, paragraph 1).

14. It would have been *prima* facie obvious for one of ordinary skill in the art at the time the invention was made to use the niosomes created by Baroli et al. to encapsulate the cationized metalloporphyrin complexes taught by Nishihara et al. Although Nishihara teaches the

metalloporphyrin complexes in liposomes, Baroli et al. teach that niosomes may be preferable to liposomes because, while they have similar utilities and can be prepared in a similar fashion, niosomes have been shown to have increased chemical stability in comparison to liposomes. Additionally, Baroli et al. disclose the ability of niosomes to encapsulate both hydrophilic and lipophilic compounds, so one skilled in the art would reasonably expect success in the encapsulation of the metalloporphyrin complexes in niosomes.

15. Additionally, with regards to claims 7 and 8, MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the

variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

16. Based on the teachings of the MPEP and KSR above, by employing the rationale in (B) above, it would be obvious for one of ordinary skill in the art to substitute other known nonionic surfactants to form niosomes upon finding that other nonionic surfactants are useful for the same quoted purpose. The success encapsulating both hydrophilic and lipophilic substances with several particular nonionic surfactants (namely, the cyclophosphazene derivatives produced by Baroli et al.) would have provided one of ordinary skill with a reasonable expectation for success in being able to encapsulate cationic metalloporphyrin complexes with niosomes formed from any of the claimed non-ionic surfactants at the time of the invention. Thus, it would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to use any of the claimed nonionic surfactants to form the claimed niosome.

Claims 1, 3 and 7-9 are rejected under 35 U.S.C. 103(a) as obvious over Nishihara et al. (US 2002/0164379), publication date November 7, 2002, in view of Baroli et al. *International Journal of Pharmaceutics,* 183 (1999), as applied to claims 1, 3 and 7-9 above, and further in view of Uchegbu et al. *Advances in Colloid and Interface Science*, 58 (1995).

17. Refer to paragraphs 11-13 above for the teachings of Nishihara et al. and Baroli et al. Taken together, the above references do not teach the specific nonionic surfactants in claim 8. Uchegbu et al. discuss many of the different options available in terms of different non-ionic

surfactants. The reference states that alkyl esters have the ability to form vesicles (p. 5, paragraph 2, last sentence). A specific example is given naming sorbitan esters as "widely used;" Figure 9D specifically lists sorbitan monooleate (Span 80) as an example (p. 14). Additionally, the fact that they have been used in foodstuffs (p. 14, line 3) demonstrates that the sorbitan esters such as Span 80 are considered safe for humans to ingest.

18. It would have been *prima* facie obvious for one of ordinary skill in the art at the time the invention was made to use Span 80 to produce the niosomes taught by the combination of the Nishihara and Baroli references above. Specifically, Span 80 is taught as a viable and widely used option for producing niosomes, and the fact that it is known to be safe for human consumption would have, at the time of the invention, provided both the motivation to do so and a reasonable expectation of success.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Fierro whose telephone number is (571)270-7683. The examiner can normally be reached on Monday - Thursday 6:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia L. Fierro/
Examiner, Art Unit 1626

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626